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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,020	07/21/2003	Michael Seul	PARSE-C4	5081

7590 10/10/2006
Bioarray Solutions
35 Technology Drive
Warren, NJ 07059

EXAMINER

DO, PENSEE T

ART UNIT PAPER NUMBER

1641

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/624,020

Applicant(s)

SEUL ET AL.

Examiner

Pensee T. Do

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47, 49, 50 and 55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47, 49, 50, 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment Entry & Claims Status

The amendment filed on July 13, 2006 has been acknowledged and entered.

Claims 47, 49, 50, and 55 are pending.

Withdrawn Rejection(s)

Rejection under 112, 2nd in the previous office action is withdrawn herein.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 47, 49, 50 and 55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 47 has been amended to recite that the "chip has a hydrophilic surface which faces the planar surface when the chip is disposed on the substrate", which is not supported in the specification of the present invention. The specification has support for a substrate comprising of well plates (hydrophilic regions) separated by hydrophobic regions, each well plate holds a microarray chip. (see figure 25a). However, the specification does not describe that the

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microarray chip has a hydrophilic surface, which opposes the hydrophilic region/well of the substrate (well plate). Applicants are required to provide support for such limitation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 47, 49, 50, 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 47 is indefinite because the claim recites that "the hydrophilic regions accommodate the chip disposed thereon" (the hydrophilic regions), which means that the chip is disposed on all the hydrophilic regions and for the chip to be disposed on all the hydrophilic regions, it has to be disposed on the hydrophobic regions as well. Therefore, it is unclear whether the chip is disposed on each hydrophilic region or all hydrophilic regions.

Maintained Rejection(s)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 47, 49, 50 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rava et al. (US 5,874,219) in view of Shivashankar et al. (US 6,139,831).

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Rava teaches a chip plate comprising a plurality of test wells (planar substrate) , each test well (hydrophilic region) having a biological chip having a molecular probe array. (see col. 1, lines 62-65). The test wells are separated by a hydrophobic region. (see col. 4, lines 24-30; fig. 3; col. 8, lines 35-46). Regarding claim 49, test wells comprise hydrophilic regions because they can accommodate aqueous sample, and are within the perimeter of the indentations of the planar surface of the substrate (plate), said indentations (wells) being surrounded by the hydrophobic regions. Regarding claim 55, Rava teaches that the chip plate is made of silicon or modified silicon. (see col. 4, lines 10-12; col. 9, lines 41-45).

However, Rava fails to teach that the chip has an array of particles deposited thereon, wherein a biological reagent is bound to the particles and that different types of particles having different biological reagent bound thereto.

Shivashankar teaches grafting an array of particles coated with a molecule such as a biomolecule, on to localized positions of semiconductor substrate (biochip). (see col. 18, lines 35-41). Shivashanka also teaches different types of particles (first and second colloidal particles) coated with different molecules (first and second DNA sequences). (see col. 18, lines 3-30).

It would have been obvious to one of ordinary skills in the art to immobilize particles, having biomolecules or different types of particles having different biomolecules immobilized thereon, as taught by Shivashanka, onto the chip/substrate as taught by Rava since both teach coating biochip with biomolecules because particles enable separation of specific biomolecules within a microfluidic chamber (wells) as

taught by Shivashanka (see col. 18, lines 40-41). Particles such as gold colloidal are also used as light scattering labels for detection purpose.

Response to Arguments

Applicant's arguments filed July 13, 2006 have been fully considered but they are not persuasive.

Applicants argue that Rava does not teach a planar substrate having several discrete hydrophilic regions separated by a hydrophobic region but rather Rava teaches test well as hydrophilic regions and a hydrophobic region as a "raised physical barrier" on the surface of the array. The present invention claims "the hydrophilic regions are separated from other hydrophilic regions by a hydrophobic region which is part of the planar surface. Rava is directed to forming a test well, there is no suggestion of having the hydrophobic region as part of the planar surface of the substrate. The present invention does not claim that the hydrophobic regions are raised with respect to the substrate surface.

The present specification describes in figure 25 a, a microplate comprising of test wells having disposed thereon a microarray chip. Claim 49 also recites that the hydrophilic regions are within the perimeter of indentations in the planar surface of the substrate, said indentations being surrounded by the hydrophobic regions. Rava teaches a microtiter plate comprising of test wells having disposed thereon a microarray chip (see figures 3 and 7). Furthermore, claim 47 recites opening "comprising" language, which fails to exclude raised hydrophobic regions. The claims also fail to recite that the hydrophobic regions are not raised.

Applicants also argue that Rava and the combined reference do not teach that the "chip has a hydrophilic surface which faces said planar surface when the chip is disposed on the substrate".

Since Rava teaches the same chip and such chip is used for the same purpose, it is inherent that such chip has a hydrophilic surface which faces said planar surface when the chip is disposed on the substrate.

Applicants further submit that Rava do not disclose "several discrete hydrophilic regions which are part of a planar surface of the substrate".

The discrete hydrophilic regions are part of the planar surface of the substrate is taught by Rava in figures 3 and 7.

Regarding the Shivashankar reference, Applicants argue that Shivashankar's semiconductor substrate is not equivalent to the claimed chip, but rather to the planar substrate. A chip disposed on a semiconductor substrate is not disclosed in Shivashankar. Applicants also argue that there is no suggestion to combine Shivashankar particles with the chip in Rava because in Rava, the chip is immobilized on the semiconductor by trapping it in a physical well, and in Shivashankar, particles are immobilized on a semiconductor with a laser. One would select one method of immobilization or the other, using both would be unnecessary, and the combination, therefore is taught away from.

Applicants' argument seems not to be on point. Shivashankar teaches a biochip array comprising a semiconductor substrate coated with particles attached with a molecule in localized positions. Shivashankar is relied upon for teaching an array of

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particles on a chip and Rava teaches disposing biochip in test well. Therefore, one of ordinary skills in the art would be motivated to combine the two references. In Rava, the chip comprising a semiconductor substrate is entrapped within a well. In Shivashanka, the particles are immobilized on a semiconductor, which is the chip. The two methods of immobilization discussed by Applicants are not related. One is a method for immobilizing the chip, and the other is a method of immobilizing the particles. The particles have to be immobilized on the chip before the chip can be entrapped within the well.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Pensee T. Do
Patent Examiner
September 26, 2006


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